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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,270	01/22/2002	Edward P. Perez	7404-318	6329

7590

11/21/2003

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EXAMINER

DAVIS, DANIEL J

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 11/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/054,270

Applicant(s)

PEREZ ET AL.

Examiner

D. Jacob Davis

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 4, 6-9, 20, 24-31, 34, 37, 38 and 43 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5, 13, 14, 22, 23, 32, 33, 35, 36 and 44 is/are allowed.
- 6) ☒ Claim(s) 1-3, 10-12, 15-19, 21 and 39-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 5) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 6) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 10-12, 15, 39, 40 and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Douglas et al. (US 6,048,352). Douglas discloses in Figs. 16-17 a device for sampling body fluid comprising a main body 94 defining a capillary channel and a lancet 96. The lancet is selectively advanceable and retractable (Col. 8, lines 7--et seq.). Because of the small annular space between the lancet and the main body, body fluid is inherently drawn into the annular space through capillary action. The device further comprises a testing element/test strip 19 that is in communication with the annular space. There is a dividing wall between passages 92 and 94 that enables communication between the two passages.

The device comprises a spring biasing means to retract the lancet (Col. 8, lines 20-22). The device further comprises biasing means to selectively advance the lancet (Col. 8, lines 14-20). The body is generally cylindrically shaped.

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Claim 16 is rejected under 35 U.S.C. 102(e) as anticipated by Douglas or, in the alternative, under 35 U.S.C. 103(c) as obvious over Douglas in view of Plum (US 5,298,224). Douglas discloses a lancet device used to obtain a blood sample but is silent regarding the material of the capillary tube. Nevertheless, inherently the capillary tube is made of biocompatible plastic because of its biocompatible nature, low cost, and inert properties. In the alternative, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the capillary tube out of plastic as taught by Plum (Col. 1, line 67—col. 2, line 2) because of its biocompatible nature, low cost, and inert properties.

Claims 21 and 41 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(c) as obvious over Douglas. The lancet of the Douglas device inherently advances between approximately 0.05 mm and 3 mm and retracts between 0 and 2 mm from the site. In the alternative, it would have been obvious to one of ordinary skill in the art at the time the invention was made to advance the lancet between 0.05 mm and 3 mm to maximize lancet control and optimize the tissue entry force. Also, it would have been obvious to one of ordinary skill in the art at the time the invention was made to retract the lancet between 0 and 2 mm from the site to remove the lancet from the target site to prevent accidental injury and to allow for blood flow.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which form the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas in view of admitted prior art. Douglas discloses a test strip but is silent regarding the manner of testing. Nevertheless, applicants admit in the specification that optically reactive test strips are known in the art as a means to test blood.

Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas in view of Graham (US 5,322,609). Douglas is silent regarding the transparency of the capillary tube. Nevertheless, Graham discloses a transparent capillary tube to allow a user to visualize the amount of blood in the capillary tube as it is being filled. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make Douglas's capillary tube transparent to visualize the amount of blood in the capillary tube as it is being filled. The entire capillary tube, including the passage defining the lancet, would be of the same transparent material to reduce manufacturing costs and processes.

Allowable Subject Matter

Claims 5, 13, 14, 22, 23, 33, 35, 36 and 44 are allowed.

Response to Arguments

Applicant's arguments regarding claim 1 have been fully considered but are not persuasive. The lancet of the Douglas device comprises a pointed tip. The capillary tube that houses the lancet in the Douglas device must draw fluid into the device. The fluid is drawn at least to (and probably beyond) the annular space defined by the tip through capillary action. Therefore, capillary action occurs within the annular space.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Jacob Davis whose telephone number is (703) 305-1232. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


DJD

November 14, 2003


MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700